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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,376	06/18/2001	John Peter Morseman	31676.0248	6731

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,376	MORSEMAN ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1 and 2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The Request for Continued Examination filed 03/01/05 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, line 5 the recitation "manner" is vague and indefinite. The recitation "manner" is a subjective term, which does not define the metes and bounds of the invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (homogenous Proximity Tyrosine Kinase Assays, Analytical biochemistry 269, 94-104 (1999)) in view of Applicant's statement regarding the sale of product (cross-linked allophycocyanin which had not been exposed to strongly chaotropic agents) (see IDS filed December 3, 2003).

Park et al disclose a method for quantitating an analyte by measuring time resolved transfer of fluorescence energy to or from a label quantitatively associated with analyte. Park et al disclose measuring the energy transferred from donor compounds to absorb light energy and then transfer this energy to cross-linked allophycocyanin. Park et al disclose the energy donor can be europium (abstract).

Park et al fail to specifically teach that the cross-linked allophycocyanin has not been exposed to strongly chaotropic agents after cross-linking, which is available for sale by Applicant more than one year prior to the filing date of this application.

Therefore, it would have been obvious to one of ordinary skill in the art to select the cross-linking agent as described in the statement provided by Applicant (see above) as an alternative for the cross-linking agent of Parks et al. And it appears both cross-linking agents would perform equally well in Time-Resolved Fluorescence Assays, therefore a skilled artisan would have a reasonable expectation of success in selecting either cross-linking agent for performing the assay.

7. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al and Applicant's statement regarding the sale of product (cross-linked allophycocyanin which had not been exposed to strongly chaotropic agents) (see IDS filed December 3, 2003) in view of Applicant's admission of prior art.

Park et al and Applicant's statement differ from the instant invention in failing to specifically teach at least two distinct donor species present in different formats.

On page 9, lines 25 – page 10, line 8 in the specification Applicant discloses that the dye of this invention can be used with any known format for FRET. Applicant discloses the known formats. It would have been obvious to one of ordinary skill in the art to incorporate the cross-linked allophycocyanin of Applicant into different well known formats of FRET as disclosed by Applicant for quantitating an analyte by measuring time resolved fluorescence of a label quantitatively associated with the analyte.

Response to Arguments

8. Applicant's arguments filed 03/01/05 and the Declaration filed 03/03/05 have been fully considered but they are not persuasive.

Applicant argues that the mere commercial availability of Applicants' product would not motivate the skilled person to use this product in the time-resolved fluorescence method disclosed in the Park publication with any reasonable expectation of achieving the benefits disclosed in the present application. Applicant directs Examiner's attention to Example 8 which begins on page 16, line 23 of the specification. Applicant argues that the Example shows that SL-APC streptavidin conjugate of the invention in TR-FRET for src kinase assay demonstrated an improved sensitivity over commercially available XL-APC. This is not found persuasive because it appears Example 8 is directed to manufacturing advantages of SL-APC (not exposed to strong chaotropic agent) and not for increased sensitivity in assays. Example 8, page 18 discloses that SL-APC is an alternative acceptor which retains all the characteristics of native APC while obtaining the same stability results as XL-APC at a reduced price and that SL-APC could provide a low cost alternative to XL-APC in this system if it provides results that did not sacrifice sensitivity. Further, page 19, lines 17-23 discloses that the dyes had signal intensity of the same magnitude, with SL-APC edging out XL-APC in signal intensity and that SL-APC provided competitive sensitivity to XL-APC without the need for extensive chemical cross-linking and purification (manufacturing advantage). Further, since it would have been obvious to one of ordinary skill to substitute the cross-linked allophycocyanin as described in the statement provided by Applicant (see above)

as an alternative for the cross-linked allophycocyanin of Parks et al, one of ordinary skill in the art would expect the combination of Parks et al and applicants allophycocyanin would posses the benefits which applicant is arguing.

With regards to the declaration filed 03/03/05, the declaration is not found persuasive because the declaration is directed to the use of cross-linked allophycocyanin (XL-APC) in a non-time-resolved manner and does not disclose that applicant's product was not sold for use in time-resolved assays and as stated above it is the Examiner's position that it would have been obvious to substitute Applicant's cross-linked agent for the cross-linked agent of Park.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
March 16, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER

03/21/05